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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte SVETLANA A. IVANOVA, DENNIS W. DAVIS, BRAD W. ARENZ, and THOMAS K. CONNELLAN

Appeal 2017-001946
Application 13/481,787[1]
Technology Center 1600

Before DONALD E. ADAMS, TAWEN CHANG, and TIMOTHY G. MAJORS, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134(a) involves claims 21 and 22 (App. Br. 2).[2] Examiner entered rejections under 35 U.S.C. § 112, second paragraph and 35 U.S.C. § 103(a). We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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[1] Appellants identify the real party in interest as "Ziolase, LLC" (App. Br. 2).

[2] "Claims 1-20 and 23-30 have been withdrawn pursuant to a restriction requirement" (App. Br. 2).

STATEMENT OF THE CASE

Appellants disclose "compositions and methods to prevent and treat biofilms" (Spec. ¶ 2). Claim 21 is representative and reproduced below:

21. A composition to prevent and treat skin and mucosal lining biofilm based infections, the composition comprising an antimicrobial and non-microbial trehalase, in an amount effective to enhance performance of the antimicrobial. (App. Br. 32.)

The claims stand rejected as follows:

Claims 21 and 22 stand rejected under 35 U.S.C. § 112, second paragraph.

Claims 21 and 22 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Olmstead,[3] Petzold,[4] Sigma,[5] and Ramage.[6]

DEFINITENESS:

ISSUE

Does the preponderance of evidence support Examiner's conclusion that the phrase "non-microbial trehalase," as set forth in Appellants' claim 21, is indefinite?

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[3] Olmstead, US 2011/0129454 A1, published June 2, 2011.
[4] Elizabeth Wills Petzold et al., *Characterization and Regulation of the Trehalose Synthesis Pathway and Its Importance in the Pathogenicity of Cryptococcus neoformans*, 74 Infection and Immunity 5877–87 (2006).
[5] SIGMA QUALITY CONTROL TEST PROCEDURE, Enzymatic Assay of TREHALASE (EC 3.2.1.28), www.sigma-aldrich.com, revised Dec. 18, 1998.
[6] Gordon Ramage et al., *Our Current Understanding of Fungal Biofilms*, 35 Critical Reviews in Microbiology 340–55 (2009).

FACTUAL FINDINGS

FF 1. Appellants define the term "[a]ntimicrobials" as "substances that kill or inhibit the growth of *microorganisms such as bacteria, fungi, or protozoans*" (Spec. ¶ 119 (emphasis added)).

FF 2. Appellants disclose that the "trehalase [enzyme] . . . has been reported to be present in many micro- and macroorganisms, including animals and plants" and "can be obtained from natural sources (plants, yeasts, fungi)" (Spec. ¶¶ 164 and 184).

FF 3. Examiner finds that the term "microbe" refers to "an organism which spends its life at a size too tiny to be seen with the naked eye, including bacteria, archaebacteria, viruses, prions, protists, and some fungi, animals and plants" (Ans. 8, citing a Google search result of the term "microbe," which refers to the Feb. 1, 2001 Michigan State University website "commtechlab.msu.edu/sites/dlc-me/zoo/ziwim.html" ("A microbe is any living organism that spends its life at a size too tiny to be seen with the naked eye. Microbes include bacteria and are archaebacterial, protists, some fungi and even some very tiny animals that are too small to be seen without the aid of a microscope")).

FF 4. Examiner finds that Appellants' "[S]pecification does not define 'non-microbial trehalase' nor 'microbial trehalase'" (Ans. 2 and 7).

ANALYSIS

As Appellants make clear, "any non-microbial trehalase is within the scope of [Appellants'] Claim 21" (App. Br. 6). Examiner, however, finds that Appellants' "[S]pecification does not define 'non-microbial trehalase' nor 'microbial trehalase'" (FF 4); that, on this record, it is unclear what the phrase "non-microbial trehalase" means (FF 2–4; Ans. 2 and 7–10); and,

thus, Appellants' claims fail to "reasonably apprise those skilled in the art" as to their scope. *Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613, 624 (Fed. Cir. 1985).

Notwithstanding Appellants' failure to define the phrases "non-microbial trehalase" or "microbial trehalase," on this record, Appellants do define the term "antimicrobial" (*see* FF 1). Therefore, we are not persuaded by Appellants' contention that because "Examiner did not reject the claim term 'antimicrobial' as being indefinite, [] there is no reasonable basis to reject the use of the term 'non-microbial trehalase' as being indefinite when the totality of all the limitations of the claim and their interaction with each other is considered" (Reply Br. 3).

Because Examiner established, on this record, that the phrase "non-microbial trehalase" is indefinite, we are not persuaded by Appellants' contention that "the ordinary and customary meaning given to the term 'non-microbial trehalase' by those of ordinary skill in the art at the time of the invention, in view of the Specification and claims themselves, is trehalase that does not originate from the microbe [that produces the biofilm] itself or any microbe" (App. Br. 5; *cf.* FF 1–3; Ans. 2 and 7–10).

CONCLUSION OF LAW

The preponderance of evidence supports Examiner's conclusion that the phrase "non-microbial trehalase," as set forth in Appellants' claim 21, is indefinite. The rejection of claim 21 under 35 U.S.C. § 112, second paragraph is affirmed. Claim 22 is not separately argued and falls with claim 21.

OBVIOUSNESS:

ISSUE

Does the preponderance of evidence relied upon by Examiner support a conclusion of obviousness?

FACTUAL FINDINGS (FF)

FF 5. Olmstead discloses "[p]hysiologically acceptable anti-biofilm compositions comprising *Serratia* peptidase and optionally one or more of bromelain, papain and a fibrinolytic enzyme," wherein "[a]dditional components can include antimicrobials" and "a disaccharidase" (Olmstead, Abstract and ¶ 19; *see* Ans. 3–4).

FF 6. Ramage discloses that "*Cryptococcus neoformans* . . . have been shown to be implicated in biofilm-associated infections" (Ramage, Abstract; Ans. 4).

FF 7. Ramage discloses that "*Cryptococcus neoformans*, an encapsulated opportunistic yeast that causes life-threatening meningoencephalitis in immunocompromised individuals, has been shown to colonize and subsequently form biofilms on ventricular shunts, peritoneal dialysis fistulas, and cardiac valves" (Ramage 341; Ans. 4–5).

FF 8. Petzold discloses that "[t]he potential pathobiological importance of trehalose in cryptococcosis was identified by two in vivo screens." First, gene expression analysis of cerebrospinal fluid from rabbits infected with cryptococcal meningitis identified trehalose-6-phosphate synthase (*TPS1*) as one of the most highly expressed genes and "[s]econd, . . . NMR studies [reported that] [o]ne of the most abundant metabolites identified in these cryptococcomas was trehalose" (Petzold 5884; Ans. 4).

FF 9. Examiner relies on Sigma to establish that "[t]rehalase from porcine kidney . . . has been commercially available from Sigma since 1998" (Ans. 6).

ANALYSIS

Based on the combination of Olmstead, Petzold, Sigma, and Ramage, Examiner concludes that, at the time Appellants' invention was made, it would have been prima facie

> obvious to use a non-microbial trehalase, such as porcine trehalase, in the composition [made] obvi[ous] by Olmstead and Petzold because porcine trehalase was commercially available at the time of the invention and it is within the skill of a worker in the art to select a known material (e.g.[,] porcine trehalase on the basis of its suitability for the intended use (i.e.[,] as a trehalase) [and] optimize the amount of non-microbial trehalase and antimicrobial in the composition used to treat biofilms [made] obvi[ous] by Petzold and Olmstead; thus, they would naturally arrive at an amount of trehalase in the composition which is effective to enhance performance of the antimicrobial; therefore, [Appellants'] claimed invention[] [is] prima facie obvious.

(Ans. 6.)

For the reasons set forth by Examiner (Ans. 12–16), we are not persuaded by Appellants' contention that, "[a]s exemplified in the laboratory results summarized in the [] Declarations of Dr. Ivanova, the claimed composition is able to enhance performance of the antimicrobials in an efficient manner and far better than antimicrobials alone" (App. Br. 13).

Petzold discloses the "pathobiological importance of trehalose in cryptococcosis," i.e., cryptococcal disease, such as "cryptococcal meningitis" (FF 8). Thus, we are not persuaded by Appellants' contention that a person of ordinary skill in this art would not have been "motivated to

select trehalase from all the disaccharidases" for use in Olmstead's composition (App. Br. 14–15; *cf.* FF 5). For the same reason, we are not persuaded by Appellants' contention that "Examiner's rationale cannot support a conclusion that the claim would have been obvious to one of ordinary skill in the art because Olmstead does not recognize the problem with trehalose in the biofilm" (Reply Br. 4–5).

For the foregoing reasons we are not persuaded by Appellants' contention that Olmstead suggests "the use of cellulases, hemicellulases, lysozyme, pectinases, amylases, DNase, β–1, 6–N–acetylglucosaminidase, and other hydrolases that are capable of digesting the exopolysaccharide, exoprotein, and nucleotide matrix of biofilms," whereas "trehalose is not an exopolysaccharide nor can it be a component of exopolysaccharides because it is a non-polymerizing sugar" (App. Br. 15; *see* Reply Br. 5).

For the same reasons, we are not persuaded by Appellants' contention that because Petzold discloses enzymes that process trehalose within a microbial cell, a person of ordinary skill in this art would not include a trehalase enzyme as the disaccharidase in Olmstead's composition (App. Br. 15–16; *see* Reply Br. 5; *cf.* FF 5).

For the foregoing reasons we are not persuaded by Appellants' contention that Examiner's conclusion of obviousness is based in hindsight (App. Br. 17).

We are not persuaded by Appellants' contention that Ramage "does not teach or suggest administering non-microbial trehalase, with or without antimicrobials," which fails to account for Ramage's contribution to the combination of Olmstead, Petzold, Sigma, and Ramage (*see* App. Br. 17; *see* Reply Br. 6; *cf.* FF 5–9).

As discussed above, Olmstead discloses a composition comprising an antimicrobial and a disaccharidase, which according to the combination of Petzold, Ramage, and Sigma may be a non-microbial trehalase (FF 5–9). As Examiner explains, "optimization of the amount of trehalase and antimicrobial in the composition would provide concentrations of trehalase which are effective to enhance performance of the antimicrobial" (Ans. 20–21). *In re Geisler*, 116 F.3d 1465, 1470, (Fed. Cir. 1997) ("'[I]t is not inventive to discover the optimum or workable ranges by routine experimentation.'") (quoting *In re Aller*, 220 F.2d 454, 456 (CCPA 1955)). Therefore, we are not persuaded by Appellants' contention that the combination of "Olmstead, Petzold, Ramage, and [Sigma] do not describe or suggest the use of non-microbial trehalase in an amount effective to enhance performance of the antimicrobial" (App. Br. 18; *see also* Reply Br. 3–4).

CONCLUSION OF LAW

The preponderance of evidence relied upon by Examiner supports a conclusion of obviousness. The rejection of claim 21 under 35 U.S.C. § 103(a) as unpatentable over the combination of Olmstead, Petzold, Sigma, and Ramage is affirmed. Claim 22 is not separately argued and falls with claim 21.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED